

Dept NIH
Albi, J.R.

June 3, 1959

Mr. J. R. Albi
Cascade Laundry and Dry Cleaners
1847 Market
Denver 2, Colorado

Dear Mr. Albi:

Please forgive my delay in replying to your letter of May 11 which was held here in Washington pending my return from the World Health Conference in Geneva. I was most pleased to have your views concerning the testing of Krebiozen as a treatment for cancer, and in reply, I am glad to provide you with information on the subject which has been made available to me by the National Cancer Institute of the Public Health Service.

It is my understanding that the National Cancer Institute has not heretofore participated in any testing of Krebiozen and has no direct knowledge of its possible usefulness in the treatment of cancer. As you may be aware from your reading, two medical groups who examined clinical data on the use of the agent have published their findings in the scientific literature. One group you referred to in your letter, namely, a subcommittee of the Committee on Research, Council on Pharmacy and Chemistry of the American Medical Association; a second group was the Committee on Cancer Diagnosis and Therapy of the National Research Council. Neither group found evidence from the data examined that Krebiozen was an effective treatment for cancer.

As you may be aware, Senator Douglas, in a speech on the Senate floor on August 22, 1958, requested that the

Public Health Service investigate the possible anti-tumor properties of Krebiozen as a treatment for human cancer. The National Cancer Institute has responded by participating in conferences and communications with the interested parties. These have been for the purpose of establishing: 1) whether available information about the agent itself, and data on its use in treating cancer, merit further evaluation of the therapy, and 2) the procedure for carrying out such an evaluation.

The general plan of procedure was discussed at a meeting on September 24 attended by Dr. Ivy, Dr. Steven Durovic of the Krebiozen Research Foundation, Mr. Frank McCulloch of Senator Douglas' staff, Dr. J. R. Heller, Director of the National Cancer Institute and other members of the Institute's staff. At the conclusion of this meeting the following statement was issued: "It is generally agreed that the evaluation of Krebiozen should be explored further and we are seeking to develop an agreed procedure that will be acceptable to the scientific community." It is believed that acceptance by the scientific community is necessary since it is only from this group that it is possible to find research scientists who have the training, knowledge and skills necessary for making a valid evaluation as to whether an agent is or is not a worthwhile addition to the group of agents already available for providing benefit to cancer patients. I am enclosing for your information three articles which tell of the extensive activities under way in the search for effective anti-cancer agents. You will note that a number of agents are helpful in prolonging comfortable life in some types of cancer, and it might be of interest to you to know that some 80 compounds^{which} have shown anti-tumor activity in experimental animals are now being evaluated in clinical studies in several institutions throughout the country. Cancer has been completely eliminated in experimental animals through the use of drugs alone, and extensive efforts by research scientists and physicians are under way in an attempt to find the correct method of doing the same for patients. Thus we have a considerable number of outstanding scientists in this country who are highly skilled in evaluating agents for their value in the management of cancer patients, and the procedures for this evaluation are well worked out.

The National Cancer Institute at the September 24 meeting suggested that a committee of scientists experienced in evaluation of the management of cancer patients and acceptable both to Dr. Ivy and the Institute be constituted to decide whether clinical trials should be undertaken and how they should be conducted. Discussion on this proposal was continued at a meeting on December 5. This conference was attended by the Senator, Drs. Ivy and Durovic, Mr. McCulloch, Dr. Heller and members of the Institute's staff. Senator Douglas expressed the opinion that the Institute's alternative proposal to his original test procedure was a proper one, and encouraged Dr. Ivy to proceed with it. Dr. Ivy was invited to define his role as consultant to the evaluating committee to which he had agreed, but preferred to do this later in writing.

In a letter to the Institute dated February 1, 1959, Dr. Ivy reverted essentially to his original proposal that he personally should be a member of "an arbitration type of committee" and "a party to the administration of the therapy and the interpretation of the results under conditions where bias cannot operate." This is a procedure which, as pointed out in two conferences attended by Dr. Ivy, could admit bias and would not be acceptable to the scientific community.

The Institute responded to Dr. Ivy's letter on February 6 by asking him to clarify his apparent rejection of the previous plan made between him and the National Cancer Institute, but in reply he reiterated the statements made in his letter of February 1. It is the desire of the Institute to get on with the evaluation of Krebiozen as soon as a scientifically acceptable procedure can be effectuated, and efforts to resolve this matter are being continued.

With regard to the statement in Dr. Shannon's testimony which you quoted, I am sure that by putting the issue "at rest" he meant that the Krebiozen question should be settled through a scientifically acceptable evaluation procedure and that he was not prejudging the outcome of such an evaluation.

Mr. J. R. Albi

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I trust that this information will be helpful to your understanding of the responsibility of the Public Health Service in approaching the evaluation of Krebiozen.

Kindest regards,

Sincerely,

John E. Fogarty
Member of Congress